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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)	Application Number	09/699,003
3 81M 7 L 700M 3	Filing Date	October 26, 2000
1000 2 1 222 1	First Named Inventor	M. Rigdon Lentz
	Group Art Unit	3762
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				U.S. PATENT DOCUM	MENTS	
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		6,878,127		Brady, et al.	04-12-2005	
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rens !		4,116,589	Rishton	09-26-1978					
7		4,189,470	Rose	02-19-1980					
		4,191,182	Popovich, et al.	03-04-1980					
		4,350,156	Malchesky, et al.	09-21-1982					
		4,362,155	Skurkovich	12-07-1982					
		4,375,414	Strahilevitz	03-01-1983					
		4,581,010	Skurkovich, et al.	04-08-1986	X				
		4,605,394	Skurkovich	08-12-1986					
		4,620,977	Strahilevitz	11-04-1986					
		4,633,417	Wilburn, et al.	12-30-1986					
		4,634,417	Korec	01-06-1987					
71		4,664,913	Mielke, et al.	05-12-1987					
7		4,801,449	Balint, Jr., et al.	01-31-1989					
NIA		4,813,924	Strahilevitz	03-21-1989					

			-	F	OREIGN PATENT DOCUMENT	S		
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ala	<i>J</i> /	DE	3302384		Lysaght, et al.	01-25-1983	`	A
	J	EP	0076665		E.I. Du Pont De Nemours	01-14-1987		1
	J	GB	2136314		Gelman Sciences, Inc.	09-19-1984		~
	V	JP	56092824	ABS inte	Terumo Corporation	07-27-1981		AL.
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¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number Substitute for form 1449A/PTO Complete if Known FORMATION DISCLOSURE **Application Number** 09/699.003 ATEMENT BY APPLICANT (use as many sheets as necessary) Filing Date October 26, 2000 First Named Inventor M. Rigdon Lentz Group Art Unit 3762 **Examiner Name** P. Bianco Sheet 15 Attorney Docket Number LEN 101 CIP CON of

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000	4,824,432	Skurkovich, et al.	04-25-1989	<b>\</b>
ر کا	4,834,973	Strahilevitz	05-30-1989	
	4,865,841	Balint, Jr., et al.	09-12-1989	
	4,963,265	Okarma, et al.	10-16-1990	
	5,037,645	Strahilevitz	08-06-1991	
	5,037,649	Balint, Jr., et al.	08-06-1991	
	5,078,673	Abrams	01-07-1992	
	5,356,374	Hogan, et al.	10-18-1994	
	5,605,690	Jacobs, et al.	02-25-1997	
	5,626,843	Skurkovich, et al.	05-06-1997	
	5,643,732	Strahilevitz	07-01-1997	\ /
	5,705,615	Lim, et al.	01-06-1998	\/
	5,730,713	Okarma, et al.	03-24-1998	X
	5,753,227	Strahilevitz	05-19-1998	
	5,840,588	Strahilevitz	11-24-1998	
	5,869,047	Blake	02-09-1999	
	5,888,511	Skurkovich, et al.	03-30-1999	/
	5,910,252	Truitt, et al.	06-08-1999	
	6,039,946	Strahilevitz	03-21-2000	
	6,197,289	Wirt, et al.	03-06-2001	
	6,221,614	Prusiner, et al.	04-24-2001	
	6,245,038	Borberg, et al.	06-12-2001	
	6,264,623	Strahilevitz	07-24-2001	
	6,287,516	Matson, et al.	09-11-2001	
لبلبا	6,428,790	Boyd	08-06-2002	\
W	6,432,405	Weinberg, et al.	08-13-2002	\
auth	6,528,057	Ambrus, et al.	03-04-2003	1/
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		U.S. PATENT DOCUM	MENTS	
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John	Number Kind Code <sup>2</sup> (if known)			
W	6,561,997	Weitzel, et al.	05-13-2003	
1/	6,569,112	Strahilevitz	05-27-2003	· /
	6,602,502	Strahilevitz	08-05-2003	
	6,602,993	Wallach, et al.	08-05-2003	
	6,607,501	Gorsuch	08-19-2003	
	6,607,723	Good, et al.	08-19-2003	
	6,627,151	Borberg, et al.	09-30-2003	
	6,630,315	Miwa, et al.	10-07-2003	\ /
	6,676,622	Strahilevitz	01-13-2004	
	6,685,664	Levin, et al.	02-03-2004	1 7
	RE 31,688	Popovich, et al.	09-25-1984	\ /
	RE 36,755	Smith, et al.	06-27-2000	
	2001/0010818	Engle, et al.	08-02-2001	V
	2001/0039392	Strahilevitz	11-08-2001	Λ
	2002/0019603	Strahilevitz	02-14-2002	7
	2002/0058031	Tung, et al.	05-16-2002	
	2002/0086276	Srivastava	07-04-2002	/ \
	2002/0107469	Bolan, et al.	08-08-2002	/ \
	2002/0111577	Sirimanne, et al.	08-15-2002	
	2002/0119147	Howell, et al.	08-29-2002	
	2002/0159995	Brady, et al.	10-31-2002	1
	2002/0183677	Chang, et al.	12-05-2002	
	2002/0187069	Levin, et al.	12-12-2002	
	2002/0197249	Brady, et al.	12-26-2002	
	2002/0197250	Brady, et al.	12-26-2002	
	2002/0197251	Brady, et al.	12-26-2002	7
Y	2003/0073822	Lofling, et al.	04-17-2003	7
OUN	2003/0118584	Glenn, et al.	06-26-2003	
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Olh		2003/0125657	Koli, et al.	07-03-2003					
.		2003/0127390	Davis, Jr.	07-10-2003					
		2003/0133929	Cham	07-17-2003	7				
		2003/0138349	Robinson, et al.	07-24-2003					
		2003/0148404	Michaelson	08-07-2003					
		2003/0163077	Kim, et al.	08-28-2003					
		2003/0195452	Hunley, et al.	10-16-2003					
		2003/0215443	Coffey, et al.	11-20-2003					
V		2004/0044301	Levin, et al.	03-04-2004					
NA		2004/0054315	Levin, et al.	03-18-2004					
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Qus	/	ABBRUZZESE, et al., "A phase II trial of recombinant human interferon-gamma and recombinant tumor necrosis factor in patients with advanced gastrointestinal malignancies: Results of a trial terminated by excessive toxicity" <i>Journal of Biological Response Modifiers</i> 9:522-527 (1990).	
ADOLF AND APFLER, "A monoclonal antibody-based enzyme immunoassay for quantitation of human tumor necrosis factor binding protein I, a soluble fragment of the 60kDa TNF receptor, in biological fluids" <i>J. Immunol. Meth.</i> 143:127-136 (1991).			
		AJANI, et al., "Phase I and II studies of the combination of recombinant human interferon-y and 5-fluorouracil in patients with advanced colorectal carcinoma" <i>Journal of Biological Response Modifiers</i> 8:140-146 (1989).	
	/	ALBERTINI, et al., "Limiting dilution analysis of lymphokine-activated killer cell precursor frequencies in peripheral blood lymphocytes of cancer patients receiving interleukin-2 therapy"  Journal of Biological Response Modifiers 9:456-462 (1990).	
	./	AREND, "Inhibiting the effects of cytokines in human diseases" Adv. Int. Med. 40:365-394 (1995).	-
		AVNER, et al., "Therapeutic murine monoclonal antibodies developed for individual cancer patients" Journal of Biological Response Modifiers 8:25-36 (1989).	
	<b>;</b> ✓	BALCEWICZ-SABLINSKA, et al., "Pathogenic <i>Mycobacterium tuberculosis</i> evades apoptosis of host macrophages by release of TNF-R2, resulting in inactivation of TNF-a" J. Immunol. 161:2636-2641 (1998).	
	J	BALIKO, et al., "Th2 biased immune response in cases with active Mycobacterium tuberculosis infection and tuberculin anergy" FEMS Immunol. Med. Micro. 22:188-204 (1998).	
7		BERMUDEZ AND CHAMPSI, "Infection with Mycobacterium avium induces production of interleukin-10 (IL-10), and administration of anti-IL-10 antibody is associated with enhanced resistance to infection in mice" Infect. Immun. 61:3093-3097 (1993).	
W	7	BEUTLER AND CERAMI, "The biology of cachectin/TNF-A primary mediator of the host response" Ann. Rev. Immunol. 7:625-655 (1989).	
Examiner's Signature		Ollmoniu Date Considered OCINOS	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

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		OTHER ART - NON PATENT LITERATURE DOCUMENTS	
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846		BLAUER, et al., "Modulation of the antilisterial activity of human blood-derived macrophages by activating and deactivating cytokines" J. Interferon Cytokine Res. 15:105-114 (1995).	
		BOMAN, et al., "Phase I study of recombinant gamma-interferon (rIFN-γ)" Journal of Biological Response Modifiers 7:438-446 (1988).	
		BRUNTSCH, et al., "phase II study of recombinant human interferon- y in metastatic renal cell carcinoma" Journal of Biological Response Modifiers 9:335-338 (1990).	
	1	BUKOWSKI, et al., "Phase I trail of continuous infusion of recombinant interleukin-2 and intermittent recombinant interferon-a <sub>2a</sub> . Clinical effects" <i>Journal of Biological Response Modifiers</i> 9:538-545 (1990).	
	1	CAULFIELD, et al., "Phase I1-lb trial of an anti-G <sub>D3</sub> monoclonal antibody in combination with interferon-α in patients with malignant melanoma" <i>Journal of Biological Response Modifiers</i> 9:319-328 (1990).	
		CHAMBRIER, et al., "Hormonal and metabolic effects of chronic interleukin-2 infusion in cancer patients" <i>Journal of Biological Response Modifiers</i> 9:251-255 (1990).	
		CHOUAIB, et al., "More insights into the complex physiology of TNF" Immunol. Today 12(5):141-145 (1991).	
		COCLET-NININ, et al., "Interferon-beta not only inhibits interleukin-1\(\beta\) and tumor necrosis factor-\(\alpha\) but stimulates interleukin-1 receptor antagonist production in human peripheral blood mononuclear cells" Eur. Cytokine Network 8(4):345-349 (1997).	
		COLMAN, et al., <u>Hemostatsis and Thrombosis: Basic Principles and Clinical Practice 2nd. Edition</u> (Colman, et al., eds.) pp. 63-67 J.B. Lippincott: Philadelphia, PA, 1987.	
	/	COX, et al., "Phase II study of human lymphoblastoid interferon in patients with multiple myeloma" Journal of Biological Response Modifiers 7:318-325 (1988).	-
Qun	· /	CREAVEN, et al., "Initial clinical trial of the macrophage activator muramyl tripeptide- phosphatidylethanolamine encapsulated in liposomes in patients with advanced cancer" Journal of Biological Response Modifiers 9:492-498 (1990).	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered.

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<sup>&</sup>lt;sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that Issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>6</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

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					Examiner Name	P. Bianco	
	Sheet	7	of	15	Attorney Docket Number	LEN 101 CIP CON	

		OTHER ART - NON PATENT LITERATURE DOCUMENTS	
Examiner's Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the Item (book, magazine, journal, serial, symposium, cetalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T²
CROGHAN, et al., "A phase I trial of recombinant interferon-α and α-difluoromethylornithine in metastatic melanoma" Journal of Biological Response Modifiers 7:409-415 (1988).			
	<b>V</b>	D'ANDREA, et al., "Interleukin 10 (IL-10) inhibits human lymphocyte interferon y production by suppressing natural killer cell stimulatory factor/IL-12 synthesis in accessory cells" <i>J. Exp. Med</i> . 178:1041-1048 (1993).	
		DIMERY, et al., "Recombinant interferon- y in the treatment of recurrent nasopharyngeal carcinoma" Journal of Biological Response Modifiers 8:221-226 (1989).	
	~	DINARELLO, "Induction of interleukin-I and interleukin-I receptor antagonist" Sem. In Oncol. 24(no. 3, Suppl. 9):81-93 (1997).	
	1	DUPERE, et al., "Patterns of cytokines released by peripheral blood leukocytes of normal donors and cancer patients during interleukin-2 activation in vitro" Journal of Biological Response Modifiers 9:140-148 (1990).	
	✓.	ENGELHARDT, et al, "Biological response to intravenously administered endotoxin in patients with advanced cancer" Journal of Biological Response Modifiers 9:480-491 (1990)	
	1	ENGELMANN, et al., "Two tumor necrosis factor-binding proteins purified from human urine" <i>J. Biol. Chem.</i> 265(3):1531-1536 (1990).	
	V	ERIKS AND EMERSON, "Temporal effect of tumor necrosis factor alpha on murine macrophages infected with Mycobacterium avium" Infect. Immun. 65(6):2100-2106 (1997).	
	/	ETGES AND MULLER, "Progressive disease or protective immunity to <i>Leishmania</i> major infection: the result of a network of stimulatory and inhibitory interactions" <i>J. Mol. Med.</i> 76:372-390 (1998).	-
1	J	FAREED, et al., "Novel antigenic markers of human tumor regression" Journal of Biological Response Modifiers 7:11-23 (1988).	
UB	~	FAVROT, et al., "Functional and immunophenotypic modifications induced by interleukin-2 did not predict response to therapy in patients with renal cell carcinoma" <i>Journal of Biological Response Modifiers</i> 9:167-177 (1990).	_

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Oen V		FERNANDES AND BALDWIN, "Interleukin-10 downregulates protective immunity to Brucella abortus" Infect. Immun. 63:1130-1133 (1995).	
	1	FOON, et al., "A prospective randomized trial of α <sub>28</sub> -interferon/y-interferon or the combination in advanced metastatic renal cell carcinoma" <i>Journal of Biological Response Modifiers</i> 7:540-545 (1988).	_
	/	FROST, et al., "Interleukin-6 induction by a muramyltripeptide derivative in cancer patients" Journal of Biological Response Modifiers 9:160-166 (1990).	
	<b>/</b>	GADDUCCI, et al., "Serum levels of soluble receptors for tumor necrosis factor (p55 and p75 sTNFr) in endometrial cancer" Anticancer Res. 16:3125-3128 (1996).	
	1/	GILL, et al., "Interferon-alpha maintenance therapy after cytotoxic chemotherapy for treatment of acquired immunodeficiency syndrome-related kaposi's sarcoma" <i>Journal of Biological Response Modifiers</i> 9:512-516 (1990).	
		GREENBLATT, et al., "The type B receptor for tumor necrosis factor-alpha" <i>Blood</i> 80:1339-1346 (1992).	
		GUSTAVSON, et al., "Pharmacokinetics of teceleukin (Recombinant human inteleukin-2) after intravenous or subcutaneous administration to patients with cancer" <i>Journal of Biological Response Modifiers</i> 8:440-449 (1989).	
	<b>\</b>	HANDZEL, et al., "Immunomodulation of T cell deficiency in humans by thymic humoral factor: from crude extract to synthetic thymic humoral factor-y2" Journal of Biological Response Modifiers 9:269-278 (1990).	
		HANK, et al., "Depressed <i>in vitro</i> T cell responses concomitant with augmented interleukin-2 responses by lymphocytes from cancer patients following <i>in vivo</i> treatment with interleukin-2" <i>Journal of Biological Response Modifiers</i> 9:5-14 (1990).	
lin		HERCEND, et al., "Immunotherapy with lymphokine-activated natural killer cells and recombinant interleukin-2: A feasibility trial in metastatic renal cell carcinoma" <i>Journal of Biological Response Modifiers</i> 9:546-555 (1990).	

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3eh	$\checkmark$	HERRMANN, et al., "Stimulation of granulopoiesis in patients with malignancy by recombinant human granulocyte-macrophage colony-stimulating factor: Assessment of two routes of administration" Journal of Biological Response Modifiers 9:475-479 (1990).	
		HÉRTLER, et al., "A phase I study of T101-ricin A chain immunotoxin in refractory chronic lymphocytic leukemia" Journal of Biological Response Modifiers 7:97-113 (1988).	
		HIMMLER, et al., "Molecular cloning and expression of human and rat tumor necrosis factor receptor chain (p60) and its soluble derivative, tumor necrosis factor-binding protein" DNA and Cell Biol. 9(10):705-715 (1990).	
		JACOBS, et al., "minimal antigenicity of intron A in human recipients demonstrated by three analytical methods" <i>Journal of Biological Response Modifiers</i> 7:447-456 (1988).	
		JAKOBSEN, et al., "Decreased antitoxic activities among children with clinical episodes of malaria" Infect. Immun. 66(4):1654-1659 (1998).	
	V	JAKSCHIES, et al., "Emergence and decay of the human Ms homolog in cancer patients during and after interferon-a therapy" Journal of Biological Response Modifiers 9:305-312 (1990).	
	W	KALMANTI, et al., "Serum levels of tumor necrosis factor soluble interleukin 2 receptor as markers of disease activity and prognosis in childhood leukemia and lymphoma" Int. J. Hematol. 57:147-152 (1993).	
		KAUFMANN, et al., "T cells and cytokines in intracellular bacterial infections: experiences with Mycobacterium bovis BCG" Ciba Fdn. Symp. 195:123-132 (1995).	
		KELLOKUMPU-LEHTINEN, et al., "Recombinant interferon-a2a and vinblastine in advanced renal cell cancer: A clinical phase I-II study" Journal of Biological Response Modifiers 9:439-444 (1990).	
		KESSLER, "Adsorptive plasma treatment: Optimization of extracorporeal devices and systems" Blood Purification 11:150-157 (1993).	
aus		KHAZAELI, et al., "Initial evaluation of a human immunoglobulin M monoclonal antibody (HA-1A) in humans" <i>Journal of Biological Response Modifiers</i> 9:178-184 (1990).	

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aur	1	KOLITZ, et al., "Phase I trial of recombinant interleukin-2 and cyclophosphamide: Augmentation of cellular immunity and T-cell mitogenic response with long term administration of rIL-2" <i>Journal of Biological Response Modifiers</i> 7:457-472 (1988).	Y
<u> </u>	V	KRIGEL, et al., "Treatment of epidemic kaposi's sarcoma with a combination of interferon-alpha 2b and etoposide" Journal of Biological Response Modifiers 7:359-364 (1988).	Y
	/	LANTZ, et al., "Infusion of tumor necrosis factor (TNF) causes an increase in circulating TNF-binding protein in humans" Cytokine 2(6):402-406 (1990).	Y
DUB	7	LASZLO, et al., "Phase I studies of recombinant interferon-y" Journal of Biological Response Modifiers 9:185-193 (1990).	4
		LAUCELLA, et al., "Papel de las citoquinas en la resistencia y patelogia durante la infeccion con Trypanosoma-cruzi" Revista Argentina de Microbiologia, 28:99-109 (1996). No francosoma	No
alk	1	LENTZ, et al., "Apheresis of low molecular weight protein fraction and the onset of labor" Journal of Clinical Apheresis 5:62-67 (1990).	
ath	V	LENTZ, "The phylogeny of oncology" <i>Mol. Biother.</i> 2:137-144 (1990).	
	/	LETTERIO AND ROBERTS, "Regulation of immune responses by TGF-β" Ann. Rev. Immuno. 16:137-161 (1998).	
	J	LITTON, et al., "Biological and clinical effects of the oral immunomodulator 3,6'Bis(2-piperidinoethoxy)acridine trihydrochloride in patients with malignancy" Journal of Biological Response Modifiers 9:61-70 (1990).	
$\downarrow$		LUCEY, et al., "Type 1 and type 2 cytokine dysregulation in human infectious, neoplastic, and inflammatory diseases" Clin. Micro. Rev. 9(4):532-562 (1996).	
dus		MAAS, et al., "Interleukin-2 in cancer treatment: disappointing or (still) promising? A review" Cancer Immunol. Immunother. 36:141-148 (1993).	
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QU7	/	MACA, "Inhibition of the growth of lewis lung carcinoma by indomethacin in conventional, nude, and beige mice" <i>Journal of Biological Response Modifiers</i> 9:568-580 (1990).	
	ľ	MARSHALL, et al., "Effects of coumarin (12-benzopyrone) and cimetidine on peripheral blood lymphocytes, natural killer cells, and monocytes in patients with advanced malignancies" Journal of Biological Response Modifiers 8:62-69 (1989).	
	J	MARSHALL, et al., "Treatment of renal cell carcinoma with daily low-dose alpha-interferon" Journal of Biological Response Modifiers 8:453-461 (1989).	
	J	MILES, et al., "induction of soluble tumour necrosis factor receptors during treatment with interleukn-2" <i>Brit. J. Cancer</i> 66:1195-1199 (1992).	
		MITTELMAN, et al., "Treatment of patients with advanced cancer using multiple long-term cultured lymphokine-activatied killer (LAK) cell infusions and recombinant human interleukin-2" Journal of Biological Response Modifiers 8:468-478 (1989).	
	J	MUSIANI, et al., "Effect of low doses of interleukin-2 injected perilymphatically and peritumorally in patients with advanced primary head and neck squamous cell carcinoma" Journal of Biological Response Modifiers 8:571-578 (1989).	
	1	NEIDHART, "Phase I study of recombinant methionyl human consensus interferon (r-metHulFN-Con)" Journal of Biological Response Modifiers 7:240-248 (1988).	
	J	ORATZ, et al. "Induction of tumor-infiltrating lymphocytes in human malignant melanoma metastases by immunization to melanoma antigen vaccine" Journal of Biological Response Modifiers 8:355-358 (1989).	
	1	ORATZ, et al., "Antimelanoma monoclonal antibody-ricin A chain immunoconjugate (XMMME-001-RTA) plus cyclophosphamide in the treatment of metastatic malignant melanoma: Results of a phase II trial" <i>Journal of Biological Response Modifiers</i> 9:345-354 (1990).	
Wh	V	PAIS, et al., "Pharmacokinetics of recombinant interleukin-2 in children with malignancies: A pediatric oncology group study" <i>Journal of Biological Response Modifier</i> s 9:517-521 (1990).	
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air	J	PAOLOZZI, et al., "Phase I trial of recombinant interleukin-2 and recombinant β-interferon in refractory neoplastic diseases" <i>Journal of Biological Response Modifiers</i> 8:122-139 (1989).	
1	/	PEREZ, et al., "A phase I trial of recombinant human gamma interferon (IFN-y4A) in patients with advanced malignancy" <i>Journal of Biological Response Modifiers</i> 7:309-317 (1988).	
		QUESADA, et al., "Recombinant interferon alpha and gamma in combination as treatment for tetastatic renal cell carcinoma" <i>Journal of Biological Response Modifiers</i> 7:234-239 (1988).	
	J	RABINOWITZ, et al., "Hemolytic anemia in a cancer patient treated with recombinant interferon-y" Journal of Biological Response Modifiers 9:256-259 (1990).	
	J	REIMANN, et al., "Suppression of the immune response by micro-organisms" Scand. J. Immunol. 31:543-546 (1990).	
		RIFFKIN, et al., "Defense against the immune barrage: helminth survival strategies" <i>Immunol. Cell Bio</i> 74:564-574 (1996)	
	/	ROMANI, et al., "T helper cell dichotomy to <i>Candida albicans</i> : implications for pathology" <i>Immunol.</i> Res. 14:148-162 (1995).	
		ROSENTHAL, et al., "The <i>in vitro</i> function of lymphocytes from 25 cancer patients receiving four to seven consecutive days of recombinant IL-2" <i>Journal of Biological Response Modifiers</i> 7:123-139 (1988).	
	V	RYBAK, et al., "Interferon therapy of relapsed and refractory hodgkin's disease: Cancer and leukemia group B study 8652" Journal of Biological Response Modifiers 9:1-4 (1990).	
	/	SARNA, et al., "Systemic administration of recombinant methionyl human interleukin-2 (Ala 125) to cancer patients: Clinical results" Journal of Biological Response Modifiers 8:16-24 (1989).	
	/	SARNA, et al., "A pilot study of intralymphatic interleukin-2. II. Clinical and biological effects" Journal of Biological Response Modifiers 9:81-86 (1990).	
am	J	SARTHOU, et al., "Prognostic value of anti-Plasmodium falciparum-specific immunoglobulin G3, cytokines, and their soluble receptors in west African patients with severe malaria" Infect. Immun. 65(8):3271-3276 (1997).	
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Ilry	SATO, et al., "induction of bone formation in an adenoid cystic carcinoma of the maxi adoptive immunotherapy involving intra-arterial injection of lympholine-activated killer recombinant interleukin-2 in combination with radiotherapy" Journal of Biological Res Modifiers 9:329-334 (1990).		
		SCHAADT, et al., "Phase II study of recombinant human tumor necrosis factor in colorectal carcinoma" <i>Journal of Biological Response Modifiers</i> 9:247-250 (1990).	
		SCHALL, et al., "molecular cloning and expression of a receptor for human tumor necrosis factor" Cell 61:361-370 (1990).	
	/	SCHEITHAUER, et al., "Combined a-2C-interferon/VMCP polychemotherapy versus VMCP polychemotherapy a induction therapy in multiple myeloma: A prospective randomized trial" Journal of Biological Response Modifiers 8:109-115 (1989).	
	<b>~</b>	SCHILLER, et al., "A phase I trial of interferon-a-2a plus cyclophosphamide, vincristine, prednisone, and doxorubicin" <i>Journal of Biological Response Modifiers</i> 8:252-261 (1989).	
		SECKINGER, et al., "Purification and biologic characterization of a specific tumor necrosis factor a inhibitor" <i>J. Biol. Chem.</i> 264(20):11966-11973 (1989).	
		SEIGLER, et al, "Melanoma patient antibody responses to melanoma tumor-associated antigens defined by murine monoclonal antibodies" <i>Journal of Biological Response Modifiers</i> 8:37-52 (1989).	
	J	SHAU, et al., "A pilot study of intralymphatic interleukin-2. I. Cytotoxic and surface marker changes of peripheral blood lymphocytes" <i>Journal of Biological Response Modifiers</i> 9:71-80 (1990).	
	J	SIDHU AND BOLLON, "Tumor necrosis factor activities and cancer therapy – A perspective" Pharmacol. Ther. 57:79-128 (1993).	
	J	SIELING, et al., "Immunosuppressive roles for IL-10 and IL-4 in human infection" J. Immunol. 150(12):5501-5510 (1993).	
<u>~</u> 1800		SPRIGGS, "One step ahead of the game: Viral immunomodulatory molecules" <i>Ann. Rev. Immunol.</i> 14:101-130 (1996).	

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Run		STEGER, et al., "Long-term remission in a patient with erythroleukemia following interferon-a treatment" Journal of Biological Response Modifiers 8:351-354 (1989).				
		STEINMETZ, et al., "Phase I study of 24-hour continuous intravenous infusion of recombinant human tumor necrosis factor" <i>Journal of Biological Response Modifiers</i> 7:417-423 (1988).				
	ン	SZŇOL, et al., "A phase I study of high-dose interleukin-2 in combination with interferon $a_{2b}$ "  Journal of Biological Response Modifiers 9:529-537 (1990).				
	TRIGG, et al., "a-interferon therapy for lymphoproliferative disorders developing in two children following bone marrow transplants" Journal of Biological Response Modifiers 8:603-613 (1989).					
		TRINCHIERI, et al., "Cytokine cross-talk between phagocytic cells and lymphocytes: Relevance for differentiation/Activation of phagocytic cells and regulation of adaptive immunity" J. Cell. Biochem. 53:301-308 (1993).				
	TRUMP et al., "Interferon-a-n1 and continuous infusion vinblastine for treatment of advanced recell carcinoma" Journal of Biological Response Modifiers 9:108-111 (1990).					
		MIEL, et al., "Recombinant interleukin-2-activated intracavitary lymphocytes: Phenotypic characteristics and effector function" Journal of Biological Response Modifiers 8:409-421 (1989).				
	V	VON HOFF, et al., "Phase II evaluation of recombinant y-interferon in patients with advanced pancreatic carcinoma: A southwest oncology group study" Journal of Biological Response Modifiers 9:584-587 (1990).				
		WALSH, et al., "Phase I study of the combination of alpha-2 interferon and cisplatinum" Journal of Biological Response Modifiers 8:11-15 (1989).				
Our		WEIL-HILLMAN, et al., "Transient decrease in IL-2 responsive lymphocytes 24 hours after initiation of continuous IL-2 infusion in cancer patients" <i>Journal of Biological Response Modifiers</i> 7:424-437 (1988).				
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-				First Named Inventor	M. Rigdon Lentz	
				Group Art Unit	3762	
				Examiner Name	P. Bianco	
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	OTHER ART - NON PATENT LITERATURE DOCUMENTS	
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	metastatic colorectal adenocarcinoma: A southwest oncology group study" Journal of Biological	
U	YELAVARTHI, et al., "Analysis of p60 and p80 tumor necrosis factor-alpha" American Journal of Pathology 143:1131-1141 (1993).	
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